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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,852

11/30/2006

Martin M. Lenhardt

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WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.

11491 SUNSET HILLS ROAD

SUITE 340

RESTON, VA 20190

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,852	<b>Applicant(s)</b> LENHARDT ET AL.	
	<b>Examiner</b> FANGEMONIQUE SMITH	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed on September 17, 2006. The Examiner acknowledges the amendment of claims 1, 3 and 8. Claims 1-14 are pending. The 101 rejection has been overcome through the amendment submitted in the Response to Office Action filed on September 17, 2007.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 5, 6, 8, 10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yost et al. (U.S. Patent Application Publication Number 2003/0191411) in view of Henriquez et al. (U.S. Patent Number 5,129,403).

In regard to claims 1, 3, 5, 6, 8, 10, 12 and 13, Yost et al. disclose device and method for determining absolute intracranial pressure in a patient. The Yost device includes sensors for measuring acoustic signals placed on the patient, and a mechanism for applying acoustic signals across the skull of the patient. The system further includes an analyzer for determining from an output of the acoustic sensors, an intra cranial pressure (paragraphs [0022]). Although Yost et al. disclose the features of the Applicant's invention including placing the sensor at different locations on the skin to gain information to assist with intracranial pressure determination as

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described above, Yost et al. do not disclose specifically placing the sensors on the eye of a patient. Henriquez et al. disclose a method and apparatus for detecting and transducing intersaccular acoustic signals. The device disclosed by Henriquez et al. includes an analyzer for determining an intracranial pressure of a patient from the output of an acoustic eye garment with sensors (col. 2, lines 63-68; col. 3, lines 1-56). The eye garment is adapted to be applied to both eyeballs of the patient having piezoelectric film as part of the sensing mechanism of the eye garment. The eye garment device is capable of determining the coherency between the two eyes of a patient under testing. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for determining absolute intracranial pressure in a patient, similar to that disclosed by Yost et al., to include sensors specifically to be adapted to an eye of a patient, similar to that disclosed by Henriquez et al., to provide an acoustic path between the brain and the detector to increase sensitivity of the device.

4. Claims 2, 4, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yost et al. (U.S. Patent Application Publication Number 2003/0191411) in view of Henriquez et al. (U.S. Patent Number 5,129,403) and in further view of Bridger et al. (U.S. Patent Number 5,919,144).

In regard to claims 2, 4, 9 and 11, the combined references of Yost et al. and Henriquez et al. disclose the features of the Applicant's invention as described above. The combined references do not specifically disclose an ultrasonic range at which the device is to operate. Bridger et al. disclose an apparatus and method for measuring the intracranial pressure of a patient. Bridger et al. further disclose the apparatus and method including steps of transmitting an acoustic signal into a cranium at frequencies of less than 100 kHz. It would have been obvious to one having

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ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for determining absolute intracranial pressure in a patient, similar to that disclosed by the combined Yost et al. and Henriquez et al. references, to include a method step and corresponding apparatus which allows the acoustic signal range to be set at a lower frequency, similar to that disclosed by Bridger et al., to provide a device and method which can measure intracranial pressure without skull penetration, which poses minimal health risks to a patient during long term monitoring (Bridger et al.- col. 1, lines 48-67; col. 2, lines 1-7).

5. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yost et al. (U.S. Patent Application Publication Number 2003/0191411) in view of Henriquez et al. (U.S. Patent Number 5,129,403) and in further view of Abreu (U.S. Patent Number 6,423,001).

In regard to claims 7 and 14, the combined references of Yost et al. and Henriquez et al. disclose the features of the Applicant's invention as described above. The combined references do not specifically disclose the ability to detect retinal artery pulsations as part of the analysis in determining intracranial pressure. Abreu discloses an apparatus and method for detecting physical and chemical parameters of a patient. Abreu further discloses having a mechanism, which is capable of determining retinal artery pulsations of the patient. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for determining absolute intracranial pressure in a patient, similar to that disclosed by the combined Yost et al. and Henriquez et al. references, to include a mechanism which allows the retinal artery pulsation to be monitored, similar to that disclosed by Abreu, to provide a means to evaluate the amount of intraocular pressure needed for vessels to open (Abreu - col. 79, lines 23-32).

***Response to Arguments***

6. Applicant argues the device disclosed by Yost et al. differs from invention because the Yost et al. device uses the acoustic signal to measure physical distance between measurement points resulting in obtaining an intra cranial pressure assessment derived through a mechanical-acoustic system. This differs from the invention since Applicant's invention uses the acoustic signal as an actual intra cranial pressure measurement. Examiner submits the claims as written merely require the device to include sensors for measuring acoustic signals in the brain and applying acoustic signals to the brain. As described in the rejection above, the Yost et al. device includes sensors for measuring acoustic signals placed on the patient, and a mechanism for applying acoustic signals across the skull of the patient. The system further includes an analyzer for determining from an output of the acoustic sensors, an intra cranial pressure (paragraphs [0022]). Examiner further submits since the skull is a part of the brain, the reference still meets the limitations of Applicant's invention as claimed. Applicant's arguments filed September 17, 2007 have been fully considered but they are not persuasive. The rejection stands.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/

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Supervisory Patent Examiner, Art Unit 3736